AMENDMENTS TO THE CLAIMS

1. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:

(a) a controlled release core comprising at least one pharmaceutically acceptable excipient and only one active drug that consists of metformin hydrochloride; and

(b) an immediate release layer surrounding the controlled release core comprising a thiazolidinedione derivative ~~containing component~~ wherein not less than 85%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0, wherein the thiazolidinedione derivative can be either pioglitazone or a pharmaceutically acceptable salt thereof and after storage at 40°C and 75% relative humidity for three months, the total thiazolidinedione related compounds or impurities in the dosage form is not more than 0.6% as determined by high performance liquid chromatography and each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.25% wherein the thiazolidinedione related compounds and impurities are:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;

(ii) (z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione;

(iii) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;

(iv) (+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-] propionate; and

(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.

2. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 90%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

3. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 95%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

4. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 100%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

5-14. (canceled).

15. (previously presented) The pharmaceutical dosage form as defined in claim 1 wherein the total thiazolidinedione related compounds are not more than 0.5%.

16. (canceled)

17. (previously presented) The pharmaceutical dosage form as defined in claim 15 wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.20%.

18. (original) The pharmaceutical dosage form as defined in claim 17 wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.10%.

19. (original) The dosage form of claim 1 wherein said controlled release core is an osmotic tablet.

20. (previously presented) The dosage form of claim 19 wherein the osmotic tablet consists of:

(a) a core comprising:

(i) 50-98% of said metformin hydrochloride;

(ii) 0.1-40% of a binding agent;

(iii) 0-20% of an absorption enhancer; and

(iv) 0-5% of a lubricant;

(b) optionally a seal coat surrounding the core; and

(c) a sustained release membrane comprising:

(i) 50-99% of a polymer;

(ii) 0-40% of a flux enhancer and

(iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin hydrochloride.

21. (canceled).

22. (canceled).

23. (original) The dosage form of claim 1 wherein said core is substantially free from any gelling or expanding polymer.

24. (currently amended) The dosage form of claim 1 wherein said controlled release of said metformin hydrochloride provides a Tmax of 8-12 hours.

25. (original) The dosage form of claim 1 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.

26. (original) The dosage form of claim 25 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.

27-34. (canceled).

35. (new) A pharmaceutical dosage form comprising:

(A) a controlled release osmotic tablet core comprising at least one pharmaceutically acceptable excipient and only one active drug that consists of metformin hydrochloride that exhibits the following dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid with a pH of 7.5 and at 37°C:

0-25% of the metformin hydrochloride is released after 2 hours;

10-45% of the metformin hydrochloride is released after 4 hours;

30-90% of the metformin hydrochloride is released after 8 hours;

not less than 50% of the metformin hydrochloride is released after 12 hours;

not less than 60% of the metformin hydrochloride is released after 16 hours; and

not less than 70% of the metformin hydrochloride is released after 20

hours; and

(B) an immediate release pioglitazone hydrochloride layer surrounding the osmotic tablet that releases not less than 90% of the pioglitazone hydrochloride from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0 and the dosage form contains not more than 0.25% of the following compounds:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;

(ii)(z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione;

(iii)(+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;

(iv)(+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy] phenyl-]propionate; and

(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.

36. (new) The pharmaceutical dosage form as defined in claim 35 wherein not less than 95%, of the pioglitazone hydrochloride is released from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

37. (new) The pharmaceutical dosage form as defined in claim 35 wherein not less than 100%, of the pioglitazone hydrochloride is released from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

38. (new) The dosage form of claim 35 wherein said osmotic tablet core is substantially free from any gelling or expanding polymer.

39. (new) The dosage form of claim 35 wherein the osmotic tablet core exhibits the

following dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid with a pH of 7.5 and at 37°C:

0-15% of the metformin hydrochloride is released after 2 hours;

20-40% of the metformin hydrochloride is released after 4 hours;

45-90% of the metformin hydrochloride is released after 8 hours;

not less than 60% of the metformin hydrochloride is released after 12 hours;

not less than 70% of the metformin hydrochloride is released after 16 hours; and

not less than 80% of the metformin hydrochloride is released after 20 hours.

40. (new) The dosage form of claim 35 that contains not more than 0.2% of the following compounds:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;

(ii)(z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione;

(iii)(+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;

(iv)(+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy] phenyl-]propionate; and

(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.

41. (new) The dosage form of claim 35 that contains not more than 0.1% of the following compounds:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;

(ii)(z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione;

(iii)(+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;

(iv)(+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy] phenyl-]propionate; and

(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.